maine standards COMPANY LLC

MAR 25 2005

510(k) SUMMARY

"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92."

"The assigned 510(k) number is: k050504."

Submitter: Maine Standards Company
Address: 765 Roosevelt Trail
Windham, ME 04062
Telephone: 207-892-1300
Fax: 207-892-2266
Contact: Christine Beach, Dir. RA/QA

Summary prepared on: February 18, 2005

Device classification name: Multi-Analyte Controls, All Kinds (Assayed and Unassayed)
Device description: Quality control material (assayed and unassayed)
Proprietary Name: VALIDATE® Urine Chemistry Calibration Verification Test Sets
Regulation Number: 21 CFR 862.1660
Product Code: JJY
Regulatory Class: Class I

Predicate Device:

1. Chem 1 Calibration Verification Test Set (K012117), manufactured by Maine Standards Company, Windham, ME.
2. Bio-Rad Liquichek Urine Chemistry Control (K934357), Bio-Rad Laboratories, Irvine, CA
3. College of American Pathologists (CAP) Urine Chemistry Survey (Calibration Verification / Linearity) LN6-B 2004, Northfield, IL

Device description: VALIDATE Urine Chemistry Calibration Verification Test Sets are human urine or serum based calibration verification materials containing multiple levels used to establish the relationship between theoretical operation and actual performance of the included analytes. There exists a linear relationship among each set of solutions.

Intended use: The VALIDATE Urine Chemistry Calibration Verification Test Sets are used by trained laboratory professionals for quantitatively verifying calibration, validating reportable ranges, and determining linearity in automated, semi-automated and manual chemistry systems for the analytes listed on the package insert.

TABLE 1: Comparison of VALIDATE Urine Chemistry Calibration Verification Test Sets to the predicate devices:

	VALIDATE Urine Chemistry Calibration Verification Test Sets	**CAP Urine Chemistry Survey**	**VALIDATE Chem 1 Calibration Verification Test Set**	**Bio-Rad Liquichek™ Urine Chemistry Control**
Catalog #	701 / 702 / 703	LN6-B 2004	101	398
Intended Use	For *in vitro* diagnostic use in quantitatively verifying calibration, validating reportable ranges, and determining linearity in automated, semi-automated and manual chemistry systems.	For use in calibration verification / linearity testing of clinical analyzers	For *in vitro* diagnostic use in quantitatively verifying calibration, validating reportable ranges, and determining linearity in automated, semi-automated and manual chemistry systems.	For *in vitro* use as an assayed quality control urine to monitor the precision of laboratory testing procedures for the listed analytes.
Analytes	**701** UA, ETOH, NA, K, CL, GLU, UUN, UTP **702** CA, MG, PHOS, CREAT AMY, p-AMY, MA, **703** serum osmo urine osmo	AMY, CA, CREAT, GLU, OSMO, UTP, PHOS, K, NA, UUN, UA	NA, K, CL, CA, PHOS, GLU, BUN, CRE, TRIG, MG, LAC, LI	AMY, CA, CL, CORTISOL, CREAT, GLU, MG, MA, OSMO, PHOS, K, UTP, NA, BUN, UUN, UA
Matrix	human urine human serum (osmo)	human urine	aqueous	human urine
Number of Levels	**701 / 702** 6 including zero **703** 5 levels	5	6 including zero	1
Preparation	Liquid, ready to use	Liquid, ready to use	Liquid, ready to use	Liquid, ready to use
Packaging	3.0 mL each level	5.0 mL each level	5.0 mL each level	10 mL
Stability	Until Expiration	14 days	Until Expiration	30 days after opening
Storage	2 to 8°C	2 to 8°C	2 to 8°C	2 to 8°C

Summary:
The information provided in this pre-market notification demonstrates that the performance of VALIDATE Urine Chemistry Calibration Verification Test Sets is substantially equivalent in form and function to CAP Urine Chemistry Survey (Calibration Verification / Linearity) LN6-B 2004, VALIDATE Chem 1 Calibration Verification Test Set (K012120), and Bio-Rad Liquichek Urine Chemistry Control (K934357) for its stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 25 2005

Ms. Christine Beach
Director, QA/RA
Maine Standards Company
765 Roosevelt Trail
Windham, ME 04062

Re: k050504
Trade/Device Name: VALIDATE® Urine Chemistry Calibration Verification Test Sets
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJY
Dated: February 25, 2005
Received: March 2, 2005

Dear Ms. Beach:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240)276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Jean M. Cooper MS, DVM

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050504

Device Name: VALIDATE® Urine Chemistry Calibration Verification Test Sets

Indications For Use:

The VALIDATE® Urine Chemistry Calibration Verification Test Sets are used by trained laboratory professionals for quantitatively verifying calibration, validating reportable ranges, and determining linearity in automated, semi-automated and manual chemistry systems for the analytes listed on the package insert.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Carol Benson

Off

Diagnostic

and Safety

K050504